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EXAMINER

RIGGS II, LARRY D

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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02/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/815,102	Applicant(s) CONWAY, ANDREW A.	
	Examiner Larry D. Riggs II	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-18 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-18 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments filed 15 November 2007 are acknowledged and entered.

Status of Claims

Claims 1-8, 11-18 and 21-23 are currently pending and under consideration.

Withdrawn Rejections/Objections

The objection to the disclosure in the Office action mailed 23 August 2007 is withdrawn in view of the amendment filed 17 August 2004.

The rejection of claims 1-8, 11-18 and 21-23 under 35 U.S.C. 112, 2nd, in the Office action mailed 23 August 2007 is withdrawn in view of the amendments filed 15 November 2007.

Terminal Disclaimer

The terminal disclaimer filed on 15 November 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Number 10/815102 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Specification

The disclosure is objected to because of the following informalities:

In the specification, page 7, line 20, the phrase "has to copies" should be replaced with "has two copies".

Appropriate correction is required.

Claim Objections

Claims 1, 11 and 21 are objected to because of the following informalities:

Claim 1 does not provide punctuation after the limitation "population" in line 4 of the first obtaining step, "obtaining actual genotype data ...". It is suggested that applicant add punctuation for clarity and grammatical correctness.

Under 37 CFR 1.75 and MPEP §608.01(m), claims with a plurality of steps should be separated by a line indentation. Likewise for further segregate subcombinations or related steps, additional indentations should be implemented.

Claims 1, 11 and 21 recite further related steps:

claim 1 recites further steps within the "analyzing" step in lines 14 – 29,

claim 11 recites further steps within the "merging" step in lines 15 – 18, and

claim 21 recites further steps within the memory storing instructions steps a – f in lines 11-28.

CLAIM OR CLAIMS: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on a separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP 608.01(i)-(p).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 11-18 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 in line 2 of the "analyzing" step and claim 21 in line 9, recite the limitation "said region". There is no clear antecedent basis for this limitation in the claim. The analyzing step refers to a region in genome of the affected people or a region in genomes of parents of the affected people, in lines 1-2 of the "analyzing" step of claim 1 and line 8-9 of claim 21. It is unclear which region the limitation refers.

Claim 1 recites the limitation "members are selected from one or both of: people affected with a genetic disease or trait in said inbred population and parents of people affected with said genetic disease or trait in said inbred population" in lines 2-3 of the "obtaining" step. Which means a member could be affected with a genetic disease or trait and be a parent. However, the "analyzing" step only includes finding a region in genomes of the affected people or a region in genomes of parents of the affected people, in lines 1-2 of the "analyzing" step. The metes and bounds of the "analyzing" step are unclear if the member being both diseased and a parent, whether their region in the genome is included in the "analysis" step.

Claim 1 in lines 3-4 of the "analyzing" step and claim 11 in lines 6-7, recite the limitation "markers exhibiting particular homozygous pairs of alleles more frequently

than would occur randomly". The metes and bounds of the limitation are unclear. The specification and claims do not provide a clear and precise definition of what encompasses "more frequently than would occur randomly". One skilled in the art would be unclear as to what the metes and bounds of the limitation may encompass.

Claim 1 in lines 1-3 of the "determining" step, claim 11 in lines 8-10 and claim 21 in lines 12-13, recite the limitation "determining a set of scores for each of said markers in said actual and estimated genotype data relative to each person for which actual genotype data was determined". The metes and bounds of the limitation are unclear. One skilled in the art would be unclear as to how markers that are in actual and estimated genotype data, are then relative to each person for which actual genotype data was determined.

Claim 1 in line 4 of the "determining" step, claim 11 in line 11 and claim 21 in lines 14-15, recite the limitation "probabilities of observing each marker given autozygosity with a founder". The metes and bounds of the limitation are unclear. One skilled in the art would be unclear as to whether the person with the marker is autozygous with a founder or what the marker relationship to autozygous pertains or what is meant by given autozygosity with a founder.

Claim 1 in lines 5-6 of the "determining step, claim 11 in lines 12-13 and claim 21 in lines 15-16, recite the limitation "probabilities of observing each marker given absence of autozygosity with the founder". The metes and bounds of the limitation are unclear. One skilled in the art would be unclear as to whether the person with the

marker is autozygous with a founder or what the marker relationship to autozygous pertains or what is given absence of autozygosity with a founder.

Claim 1 in line 25, claim 11 in line 18 and claim 21 in line 20, recite the limitation "whether said marker is autozygous and whether said marker is not autozygous". The metes and bounds are unclear. One skilled in the art would not understand how a marker, defined as a genetic sequence in the specification, page 7, line 18, can be or not be autozygous. An organism carrying two alleles and can be autozygous but it is unclear how a single sequence can be autozygous.

Claim 6 recites the limitation "the scores" in line 2. There is insufficient antecedent basis for this limitation in the claim because there are numerous scores defined in independent claim 1 and dependent claims 2-5.

Claim 16 recites the limitation "the scores" in line 2. There is insufficient antecedent basis for this limitation in the claim because there are numerous scores defined in independent claim 11 and dependent claims 12-15.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8, 11-18 and 21-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn a method of using statistical analysis of genetic data from an inbred population to determine likely genetic regions for a recessive genetic disease or trait, comprising the steps of:

obtaining actual genotype data from members of an inbred population, wherein said members are selected from one or both of: people affected with a genetic disease or trait in said inbred population and parents of people affected with said genetic disease or trait in said inbred population,

obtaining estimated genotype data for said inbred population; and analyzing the actual and estimated genotype data to find a region in genomes of the affected people or a region in genomes of parents of the affected people, wherein said region includes markers exhibiting particular homozygous pairs of alleles more frequently than would occur randomly and said step of analyzing is performed using a computing device, and wherein said step of analyzing comprises:

determining a set of scores for each of said markers in said actual and estimated genotype data relative to each person for which actual genotype data was determined, with the set of scores for each marker including at least first scores generated to determine probabilities of observing each marker given autozygosity with a founder and second scores generated to determine probabilities of observing each marker given absence of autozygosity with the founder;

merging the set of scores for each marker to produce a merged score for each marker, wherein said step of merging comprises;

computing for each of said markers a ratio of said first scores to said second scores, wherein each merged score indicates at least in part a statistical distinction between whether said marker is autozygous and whether said marker is not autozygous;

examining the merged scores to determine one or more contiguous regions of markers by locating a statistically significant gap in sums of said merged scores for non-overlapping contiguous regions of markers, wherein contiguous regions of markers having scores above the gap are determined to be said one or more contiguous regions of markers;

selecting from said one or more contiguous regions of markers at least one contiguous region likely to contain a recessive allele associated with said genetic disease or trait; and

storing said at least one contiguous region likely to contain a recessive allele associated with said genetic disease or trait to a computer-readable memory.

Since the claimed invention involves a mathematical algorithm, which is a judicial exception, the following analysis of facts of this particular patent application follows the rationale suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at

<http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm>).

The Guidelines states:

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- The claimed invention "transforms" an article or physical object to a different state or thing.*
- The claimed invention otherwise produces a useful, concrete and tangible result.*

In the instant claims, there is no physical transformation by the claimed invention, thus the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result.

In determining if the instant claims have a useful, tangible, and concrete final result, the Examiner must determine each standard individually. For a claim to be "useful", the claim must produce a final result that is specific, substantial and credible. For a claim to be "tangible", the claim must set forth a practical application of the invention that produces a real-world final result. For a claim to be "concrete", the process must have a final result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete final result in the claim itself, and the claim must be limited only to statutory embodiments. Thus if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

Method claims 1-8, 11-18, 22 and 23 do not produce a tangible final result. A tangible requirement requires that the claim must set forth a practical application of the questionnaire and scoring of answers, to produce a real-world result. The instant claims are drawn to a method of determining likely genetic regions for a recessive genetic

disease or trait. However, the last step of the claims includes storing a contiguous region to a computer-readable memory. It is unclear if the computer-readable memory is readable by a user, or if a user would have access to said memory in a tangible form. Since the claim itself must include a useful, concrete and tangible final result, the instant claims are non-statutory.

Regarding the system claim 21, because the method claims are drawn to nonstatutory subject matter for not producing a useful, concrete and tangible result, the system that performs the process also does not produce a useful concrete and tangible result, thus also drawn to nonstatutory subject matter. The last instructional step (f) is storing a contiguous region to a computer-readable memory.

This rejection could be overcome by amendment of the claims to recite that a specific final result of the process is outputted to a user, or by including a result that is a physical transformation.

It is noted that the disclosure does not support the limitation "reported to a user", in the Final Office Action mailed 22 March 2007. The applicants are cautioned against introduction of new matter in an amendment.

Conclusion

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry D. Riggs II whose telephone number is 571-270-

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3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM,
ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's
supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number
for the organization where this application or proceeding is assigned is 571-273-8300.

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| /LDR/
Larry D. Riggs II
Examiner, Art Unit 1631

/ Shubo (Joe) Zhou/
Shubo (Joe) Zhou, Ph.D.
Primary Examiner